REMARKS/ARGUMENTS

Claims 1-5, 7-40, 45, 47-54 are currently in the application. Claims 12, 18, 23-27, 31-35, 37-40, 45, and 47-48 are withdrawn from consideration.

Rejections under 35 USC §103(a)

Claims 1-5, 7-11, 13-17, 19-22, 28-30, 36, and 49-54 are rejected as obvious over Jacobsen (US 6,045,534) and further in view of Flaherty (US 7,303,549), and further in view of Ueda et al. (US 7,252,653 and Rise (US 5,752,930).

Applicant traverses.

A. The rejection does not meet the legal requirements for rejecting claims under 37 CFR 1.104.

Rule 37 CFR 1.104 requires … "(2) In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified." (emphasis added)

The rejection does not specify which of the cited references is specifically applies to each rejected claim. The rejection states in effect that each and every one of the claims is rejected under a combination of all four references. The rejection lacks the specificity necessary for the Applicant to know which one or more of the references apply to each specific claim. The Applicant is expected to sort through all the references, and to figure out on his own which ones of the four references apply to claim 1, to claim 2, etc. It is the Office's responsibility to specify which of the cited references is specifically applied to each rejected claim. The rejection fails to so specify the references to the specific claims.

Consequently, the Applicant asks that the rejection be withdrawn, and that, at the least, a rejection be issued that more particularly specifies the prior art references applied to each claim or groups of claims.

B. The rejection fails to state a prima facie obviousness rejection

Notwithstanding the failure of the action under Rule 37 CFR 1.104, the rejection also fails to state a prima facie obviousness rejection.

Jacobsen (US 6,045,534) discloses: an autoinjection device that utilizes a piston-like assembly and a propellant to automatically inject a single dose of a drug into a person when the propellant is activated [Field of the Invention]; an autoinjection device that quickly administers the drug [Summary of the Invention, column 2 lines 39-40]; a pressure source preferably comprises a highly combustible material, such as a propellant, that forms a gas when ignited, and an igniter to ignite the combustible material [Summary of the Invention, column 3 lines 17-19]; the ignition of the propellant (the combustible material) occurs in short period of time, 500 milliseconds [column 5 lines 3-8]; that after ignition, circuitry is activated and heats another resistor 55 for a period of time (e.g., 0.5 seconds) to melt a solder, which allows the gases generated by ignition of the propellant to escape and allow a coil spring to retract the needle [column 5 lines 18-26].

Flaherty is attributed to teaching the use of an adhesive layer on the housing of an injection device that allows the flexing of the skin during attachment and aids the patient's comfort. Flaherty discloses a drug infusion device, which contemplates infusing the drug from a reservoir through a cannula of the period of three days [column 37 line 60 through column 38 line 2].

With regarded to the alleged combination of Jacobsen and Flaherty, Applicant traverses. Jacobsen teaches an autoinjector that injects a dose of vaccine and retracts the needle in something like 1 second. Flaherty teaches a drug infusion device that meters the drug through an inserted cannula over a several-day period. It is not predictable, and frankly inconceivable, that a person of ordinary skill would consider a combination of these two references teaching different devices that deliver a fluid through a needle over such immensely different period frame. Furthermore, it is unpredictable that one of ordinary skill would consider applying an adhesive layer on the autoinjector of Jacobsen; Jacobsen discloses or suggests applying the device to the skin of the patient for not more than about a second. There simply no reason for one to attach an adhesive layer to the device. Put simply, a person of ordinary sill would not have recognized that the result of this combination was predictable. And, there is no teaching, suggestion, or motivation, in either of the references or in the knowledge generally available to one of ordinary

skill in the art, to combine the teachings of these two references.

It is also known that pain is associated with the injection of medicaments as the rapid accumulation of the liquid medicament can tear the muscle tissue or other body tissue. (See Applicant's specification, page 1, last paragraph.) In Jacobsen, the injection of the liquid appears to occur in about a second or so, comparable to conventional hand-held syringe injections, which would reasonable effect such pain. It would thus not be predictable to employ a smaller diameter needle, as taught by the present invention, in the device of Jacobsen because the person of ordinary skill would give no consideration to the avoidance of pain associated with a smaller diameter needle. Besides, the use of a smaller-diameter needle in the device of Jacobsen would inherently increase the back pressure of the injection liquid within the device, and perhaps decrease the effective flow rate, which appears contrary to the teaching in Jacobsen of an autoinjection device that quickly administers the drug within about a second.

The rejection also states that **Ueda** and **Rise** show how a person of ordinary skill would find it obvious to try and modify the prior art reference to the needle and the flow rate that meets the needs of the infusion rate that is prescribed by the physician and thus fulfilling the claim requirements of the Applicants' invention.

Applicant traverses.

The **Ueda** et al. reference (US 7,252,653, filed (PCT) Jan 23, 2002), discloses a tapered injection needle affixed to the end of a hand-held syringe for injecting the liquid. The rejection states that Ueda et al. discloses the "benefit of having needles with the specific claimed dimensions". Ueda et al. teaches a non-standard needle that tapers from the small-diameter injection end to an anchoring part 22, which is sized larger that the insertion part 21 of the needle in order to reduce liquid flow resistance (column 7, lines 5-8) and to improve attachment of the needle to the supporting part 3 of the hand-held syringe (column 7, lines 27-30). Ueda notes that the small diameter injection end or tip provides less injection (needle insertion) resistance and pain (column 1, lines 55-67), but creates significant backpressure when injecting liquids by hand, which can make it difficult to inject the complete dose (column 2, lines 5-11) or can result in a larger, heavier device that is harder to handle by hand (column 2, lines 20-33).

The rejection alleges an "obvious to try" standard for combining the needle size of Ueda with the device of Jacobsen. However, the "obvious to try" standard requires that there be "(2) a finding that there had been a finite number of identified, predictable potential solutions to the

recognized need or problem; (and) (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success." The Ueda teaching clearly fails the "obvious to try" criteria. The needle taught in Ueda requires a needle that tapers from the injection end to an anchoring part, which is purposely sized larger that the insertion part of the needle in order to reduce liquid flow resistance and to improve attachment of the needle to the supporting part of the syringe. None of the alleged "finite number" of needles of Ueda could possibly be substituted for the needle in Jacobsen, with any reasonable expectation of success. Therefore, a person of ordinary skill in the art would not have recognized or predicted that applying the technique of Ueda et al. would have yielded predictable results in the device of Jacobsen, which requires that the needle have both ends shaped to pierce – at one end, the skin, and at the other end, the puncture seal of the reservoir, while the non-standard needle of Ueda clearly does not.

Also, both the Jacobsen and the Ueda devices are hand-held devices configured to deliver the liquid medicament as quickly as possible into the body. Neither Jacobsen nor Ueda provide housing having a base for attachment to the skin of the patient, as provided by Applicant's claims.

The **Rise** reference (US 5,752,910) teaches using a syringe with a hypodermic needle 16 to rapidly fill an under-the-skin injection device through a septum 18 in a port 14 disposed in the injection device, as seen in Fig. 1 and described at column 2, line 66 to column 3, line 6. The flow rate identified by the examiner in the action in Rise is 1 μL/min to 5000 μL/min. However, a person of ordinary skill consulting Rise would unquestionably recognize that this alleged flow rate occurs only in short bursts covering a first time period ranging from 0.01 seconds to 2.0 seconds, while the flow rate is shut off or zero during a succeeding second time period that runs from 8 seconds to 672 hours. It makes no sense that this flow rate would be construed as a constant flow rate. The only disclosure in Rise of an average flow rate is found in claim 7, namely 0.01 μL/hr (2.8×10^{-6} μL/sec) to 20 μL/min (0.33 μL/sec), which is completely outside the Applicants' claimed flow rates.

Finally, the rejection makes a general allegation that "the flow rate and the size of the needle diameter . . . are well known variables that depend on the type of medication, size of the apparatus and form of treatment and are constantly modified depending on medical procedure." Applicant respectfully considers that such statement is a generalized opinion and is without any

factual basis, and cannot replace or substitute for the identification of specific prior art references that anticipate or make obvious Applicant's claimed invention.

Therefore, Applicant believes that the rejection fails to state a *prima facie* obviousness rejection against any of the claims.

Rejoinder of Withdrawn Claims

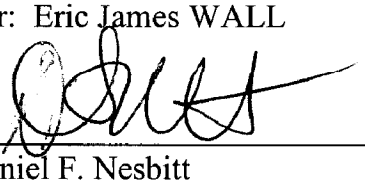
In view of the arguments clearly distinguishing the examined claims over the prior art of record, Applicant requests rejoinder of the withdrawn claims 12, 18, 23-27, 31-35, 37-40, 45, and 47-48, and consideration of the patentability of the same.

Conclusion

Applicant believes a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicant requests rejoinder of the withdrawn claims and a prompt allowance of all claims.

Respectfully submitted,

For: Eric James WALL

By: 

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